PREVENTION

Randomised controlled trial of alternative male and female condom promotion strategies targeting sex workers in Madagascar

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Objectives: To assess whether individual clinic-based counselling as a supplement to peer education for male and female condom promotion leads to greater use of protection and lower STI prevalence among sex workers in Madagascar already exposed to intensive male condom promotion.

Methods: In two public dispensaries in Madagascar, a total of 901 sex workers were randomly allocated between two alternative male and female condom promotion interventions: peer education only, or peer education supplemented with individual clinic-based counselling. Participants were followed for 12 months. Every 2 months they made clinic visits, where they were interviewed on condom use. Peer educators counselled all participants on condom use as they accompanied their assigned participants to study visits. Participants assigned to receive the supplemental intervention were counselled by a trained clinician following study interviews. Participants were tested and treated for chlamydia, gonorrhoea and trichomoniasis every 6 months. We used logistic regression to assess whether the more intensive intervention was associated with reduced STI prevalence. Use of protection with clients and non-paying partners was assessed by study arm, site, and visit.

Results: There was no statistically significant association between study arm and aggregated STI prevalence. No substantial differences in levels of reported protection were noted between study groups.

Conclusions: This study found little evidence for gains from more thorough clinical counselling on male and female condom use. These findings suggest that less clinically intensive interventions such as peer education could be suitable for male and female condom promotion in populations already exposed to barrier method promotion.

Prevention interventions targeting sex workers traditionally focus on encouraging male condom use to reduce the risk of sexually transmitted infection (STI). The well documented obstacles to consistent male condom use underscore the need for complementary prevention strategies.[1–3] Recently, selected STI prevention programs targeting sex workers have added female condom distribution to their services. The female condom is as effective as the male condom in preventing STI transmission;[4–6] in some settings, availability of this female-initiated method in addition to male condoms has been associated with increased levels of protection.[7–11] Increases have been attributed to the additive effect achieved through use of the female condom in situations in which male condom use is not possible. Additionally, a woman's capacity to propose use of an alternative prevention method has reportedly heightened her bargaining power to insist on male condom use, further contributing to increases in protection.[12]

Still uncertain are the strategies necessary for successful female condom promotion. The most thoroughly documented interventions have been more intensive than those that typically support large-scale male condom distribution. Most include multiple components with repeated educational sessions delivered by professionals in health facilities.[13–20] The replicability and sustainability of intensive promotion strategies are limited in resource-poor settings where the need for STI prevention options is most dire.

The effectiveness of simpler female condom interventions warrants examination. The study reported on here, conducted with sex workers in Madagascar, examined the effect of two male and female condom promotion interventions: peer education only, and peer education supplemented with individual clinic-based counselling. This investigation is the conclusion of a two-phased study. The first phase, conducted with the same cohort, revealed higher rates of protected sex and lower STI prevalence among sex workers exposed to clinic-based counselling as a supplement to peer education, in the presence of male condom promotion only.[21] In the phase reported here, we tested the hypothesis that an intervention including both male and female condoms similarly will achieve greater success among users benefiting from more intensive, individualised clinic-based counselling.

METHODS

Study design

We conducted a randomised controlled trial in two public sector clinics in Antananarivo and Tamatave, Madagascar. During the study's initial 6-month phase, reported elsewhere,[21] A total of 1000 female sex workers were randomised to two study arms: peer promotion of male condom use supplemented by risk-reduction counselling by a clinician, versus male condom promotion by peer educators alone. Reported here is the trial's second phase, a 12-month period during which participants had access to male and female condoms. Participants were scheduled to make visits at 2-month intervals. To assess the STI outcome, study physicians conducted clinical exams and collected specimens at 6, 12 and 18 months. At those, and at intervening visits (8, 10, 14, 16 months), participants were

Abbreviation: STI, sexually transmitted infection

interviewed about their sexual activity and condom use with clients (paying sexual partners) in the last 30 days and non-paying partners (last act).

The study was approved by the ethical committees of the Laboratoire National de Référence (LNR) VIH/SIDA in Madagascar, and Family Health International.

Study population and randomisation

For the trial's initial phase we enrolled 1000 self-identified female sex workers. The 901 participants who completed the 6-month visit of the trial's first phase were randomised again to receive in Phase 2 either prevention counselling by peer educators (hereafter referred to as the peer group), or peer counselling plus clinic-based counselling (peer+clinic group; fig 1). Following CONSORT guidelines,[22] group assignment was guided by a computer-generated random allocation list stratified by study site created at FHI using a block permuted approach with block sizes of 20, 10 and 4. Assignment to the Phase 2 study arm was accomplished through use of sequentially-numbered sealed, opaque envelopes containing the group assignment. Due to a programming error, the second round of randomisation was inadvertently imbalanced, with a disproportionately high number of participants who received the more intensive intervention in the first phase receiving the same in the second phase. Four study participants (one in Antananarivo and three in Tamatave) did not receive their assigned allocation at Phase 2, but were included in their assigned study arm during analyses (intent-to-treat analysis). At month 12, 863 participants provided STI data, and 818 women completed a study visit at 18 months. The study had greater than 80% power to detect a 10% difference in STI prevalence between the two groups (2-sided), with alpha = 0.05. Clinic staff and participants were not blinded to group assignment, but laboratory staff were blinded.

Study interventions

Following the methods used in the study's first phase, peer educators trained by the study provided all participants risk-reduction counselling that included male and female condom promotion. Counselling took place while the peer educators accompanied their assigned participants to bi-monthly interviews at the clinics and during ad hoc contacts in the community. Peer educators in Tamatave, trained in social marketing, sold condoms at the lowest price available in that city. Peer educators in Antananarivo encouraged participants to purchase condoms from existing social marketing outlets. In both sites, male and female condoms were priced equally. Peer educators were in frequent contact with supervising clinic personnel. The study manager also met monthly with peer educators to monitor and encourage mastery of counselling and other duties.

Participants randomly assigned to the peer+clinic arm additionally received bi-monthly clinic counselling sessions, delivered by a nurse in Tamatave and a physician in Antananarivo who received two 5-day training sessions designed and led by a consultant specialising in behaviour change communication. The counselling sessions, lasting approximately 15 minutes, involved two-way exchange of information concerning individual risk assessment; transmission and verification of basic knowledge about STI/HIV; dual protection; demonstration of use of both types of condoms with opportunity to practice using models; reinforcement of skills for negotiating condom use; and promotion of the ''no condom = no sex'' policy. Clinicians offered sample male and female condoms and advised participants to purchase additional condoms from a peer educator or social marketing agent. The study manager monitored performance and encouraged the clinic-based counsellors through monthly visits.

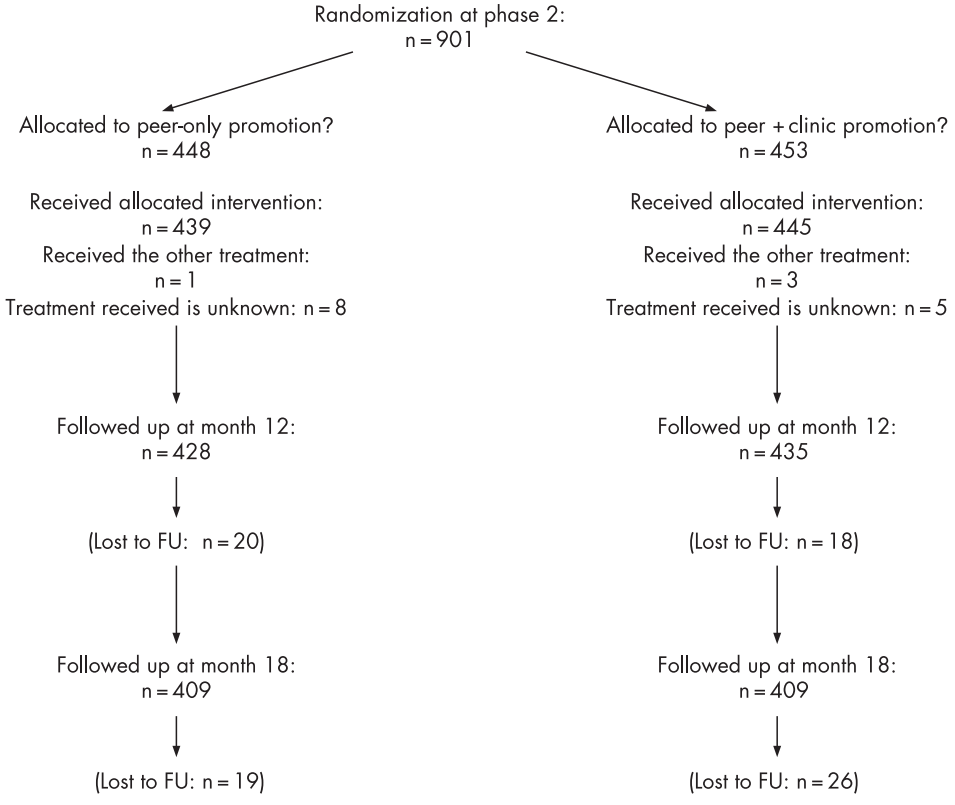

Figure 1 Participant flowchart based on STI analyses.

Clinical and laboratory methods

Methods for obtaining, storing, transporting, and testing specimens are described in detail elsewhere.[21] To summarise, at each site one physician performed all examinations. After urine and venous blood specimen collection, a swab sample was collected from the posterior fornix for immersion in InPouch (BioMed, San Jose, California, USA). InPouch specimens were evaluated microscopically for *Trichomonas vaginalis* on the day of collection and daily during 5 days of incubation at 37°C. Frozen urine samples were shipped on dry ice to the University of North Carolina in Chapel Hill, North Carolina for ligase chain reaction testing (Abbott LCx Probe System, Abbott Laboratories, Abbott Park, Illinois, USA) for *Neisseria gonorrhoeae*, and *Chlamydia trachomatis*.

All participants were treated presumptively for gonorrhoea and chlamydia with single-dose ciprofloxacin and azithromycin at baseline and the 6- and 12-month visits. Participants with trichomoniasis (direct identification and/or positive culture) received single-dose directly-observed treatment (2 g metronidazole). At the 18-month visit, participants were treated in accordance with national guidelines for syndromic management of STIs.

Statistical analysis

The study measured the impact of supplementing peer promotion of male and female condoms with individualised clinic-based risk-reduction counselling. One of the primary outcomes was STI prevalence; given the highly effective presumptive treatment administered following each round of clinical exam, we regard prevalent infections as a measure of 6-month incidence. We computed prevalence of each STI outcome separately, and then aggregated gonococcal, chlamydial and trichomonal infections into a dichotomous STI outcome. Statistical tests were deemed significant at the $\alpha = 0.05$ level. Women with missing data for a particular endpoint were excluded from that analysis.

We ran a logistic regression model to assess whether exposure to the more intensive intervention in Phase 2 was associated with reduced STI prevalence at month 18. The primary model adjusted for site and Phase 1 intervention group. Interaction terms between site and intervention groups in both phases were initially included. Interaction terms with p values greater than 0.10 were eliminated; only the interaction term for site and Phase 2 intervention was retained. Odds ratio estimates of Phase 2 intervention effect, stratified by site, were computed based on linear combinations of the corresponding model coefficients. To control for potential confounding, we ran a secondary model with the following pre-specified control variables, as measured at month 6 (Phase 2 baseline): age, aggregate STI, number of paying partners in the last 7 days prior to interview, and having any non-paying partner in last 7 days. Site-specific odds ratio estimates were computed as above.

To examine the other primary outcome (reported condom use), we computed the proportion of protected vaginal sex acts with clients for each participant by dividing reported number of sex acts in the past 30 days in which condoms were used by the total reported number of sex acts in the period. Mean values were computed by visit, site, and study arm. Among participants who had a non-paying partner in the past 30 days, we computed the proportion reporting use of protection in the last sex act. Additionally, we computed the proportion of women reporting any female condom use in the past 30 days with paying partners. Statistical tests were not performed to assess differences in reported condom use due to the inherent imprecision of self-reported condom use behaviour.[23–25]

RESULTS

Sociodemographic characteristics

Randomisation produced treatment groups similar in all important respects (table 1). The sample profile is similar to that of the full sample of 1000 participants interviewed at Phase 1 baseline.[21] Most Antananarivo participants were divorced or separated but currently in a stable union. Slightly fewer Tamatave participants reported having a steady boyfriend, and no participants reported cohabitation. Mean participant age was consistent across the sites and intervention groups, averaging 27 to 31 years. Few participants reported using highly effective contraception.

STI prevalence

Throughout the 12 months of female condom availability, the declines in site-specific prevalence of individual STIs among the peer+clinic group were largely similar to those in the peer-only arm (table 2). Two exceptions noted in Tamatave were gonorrhoea prevalence in the peer-only group, which increased by 1.2% between study visits, and trichomoniasis prevalence in the peer+clinic group, which increased by 3.6%. Logistic regression analysis of the aggregated STI outcome revealed no statistically significant association between study arm and aggregate STI (table 3). Similarly, the site-specific results failed to show a significant intervention effect; paradoxically the clinic intervention was associated with a marginally significant higher STI prevalence in Tamatave only. These results remained unchanged when we ran the secondary model to adjust for potential confounders. (Data not shown.)

Condom use

The mean proportion of sex acts with clients in the past 30 days in which protection was used, stratified by intervention group and site is presented in fig 2. Reported protection increased over time in all four groups, trending from 76–82% at Phase 1 (month 6) to 84–91% of acts following 12 months of male and female condom promotion (month 18). Antananarivo participants receiving peer education alone achieved the steepest increase during the male+female condom period. The Tamatave peer+clinic group showed the most modest increases in reported use of protection. The proportion of participants reporting any use of the female condom with a paying partner in the past 30 days was greater among Antananarivo participants, with no important differences between intervention groups (fig 3).

For three of the four intervention- and site-specific groups, the proportion of study participants reporting use of protection in their last act with a non-paying partner held steady throughout 12 months of female condom availability, never surpassing the level of protection achieved at the end of the male condom-only phase (fig 4). The exception was the Antananarivo peer+clinic group, showing a 10% increase in the proportion of participants reporting use of protection in their last act with a non-paying partner. Examination of the distribution between male and female condom use in that last act revealed that greater use of male condoms and female condoms contributed to this difference. (Data not shown.)

DISCUSSION

This study is one of few randomised trials to compare alternative strategies for simultaneous promotion of male and female condom use. The results fail to show an association between intervention intensity and either STI prevalence or reported use of protection. Sex workers exposed to individualised counselling from a trained clinician were no more apt to avoid STI acquisition or report greater increases in protection with clients than sex workers exposed to peer education alone.

Table 1 Marital status, age and contraceptive use at month 6 by site and intervention group (n = 901)

	Antananarivo		Tamatave	
	Peer only (n = 230)	Peer+clinic (n = 229)	Peer only (n = 210)	Peer+clinic (n = 219)
	n (%)	n (%)	n (%)	n (%)
Marital status:*				
Single w/o steady boyfriend	5 (2.2)	4 (1.7)	118 (56.2)	116 (53.0)
Single w steady boyfriend	127 (55.2)	129 (56.3)	88 (41.9)	86 (39.3)
Cohabiting	71 (30.9)	76 (33.2)	0 (0.0)	0 (0.0)
Separated/divorced	150 (65.2)	142 (62.0)	1 (0.5)	3 (1.4)
Others	23 (10.0)	29 (12.7)	5 (2.4)	16 (7.3)
Age:				
Mean	28.4	29.5	29.9	28.7
SD	8.09	8.55	7.85	7.55
Contraceptive:*				
Pill	9 (3.9)	18 (7.9)	20 (9.5)	16 (7.3)
Injectable	20 (8.7)	23 (10.0)	13 (6.2)	12 (5.5)
Others	3 (1.3)	3 (1.3)	3 (1.4)	3 (1.4)
None used	198 (86.1)	185 (80.8)	176 (83.8)	191 (87.2)

*Study participants could choose more than one type of marital status and contraceptive method.
SD, standard deviation.

Furthermore, the level of reported female condom use with clients was not associated with intervention group assignment.

This study's first phase, during which only the male condom was offered, showed a weak association between intervention intensity and behavioural and STI outcomes.[21] One possible explanation for the divergent results reported here is that participants had been saturated with prevention messages after 6 months of male condom promotion. The additive benefit of individualised clinic-based counselling could have been negligible in the second phase if participants were maximally convinced of the importance of consistent use of protection and skilled in negotiating for use of protection. The instruction required for mastery of a new method such as the female condom could be minimal compared to the coaching required for successful use of barrier method protection in general. Efficiencies might therefore be gained by introducing the female condom into prevention programs with strong, ongoing male condom promotion. Such a staged approach to method introduction could minimise use of the female condom for acts that could be protected by the cheaper and equally effective male condom. This study did not attempt to address the challenges associated with the female condom's cost; donation of the devices permitted female condom to be sold at the same price as the male condom, a situation possible only in heavily subsidised programs.

Given recent campaigns for dramatic global expansion of female condom distribution,[26] the feasibility and replicability of promotion strategies are of paramount importance. This study's results challenge assumptions about the benefits achieved through intensive female condom promotion interventions. This study found little evidence of an advantage, measured in terms of either reported behaviours or STI outcomes, achieved through more thorough counselling on male and female condom use. These findings suggest that peer education could serve as a suitable alternative to clinic-based male and female condom promotion. Such equivalence is particularly important for settings with health manpower shortages where clinicians' time is needed for other STI control services, such as diagnosis and treatment. The results have implications for settings in which lay counsellors are assuming an increasing role in service delivery, such as HIV counselling and testing.

This study's results must be interpreted in light of its limitations. Despite our attention to recommendations made by methodological scholars for improving condom use measures,[27] we recognise the likelihood of over-reporting of condom use. Further, social desirability bias could be differential: participants benefiting from the more intensive intervention might have been especially prone to over-report condom use. Given these limitations, we omitted statistical tests for behavioural data as such assessments might suggest an unwarranted level of precision. Nonetheless, we believe the condom use data are informative. The rough parity in reported levels of condom use in the two intervention groups supports the finding that sex workers benefiting from peer education alone are at no disadvantage.

A potential limitation of the STI results is the lack of certainty about treatment effectiveness. With close participant follow-up and highly effective treatment, we presumed infections were

Table 2 STI prevalence (chlamydia, gonorrhoea, trichomoniasis, and aggregate STI) at months 6, 12, and 18, by site and intervention group

	Chlamydia			Gonorrhoea			Trichomoniasis			Aggregated STI		
	6	12	18	6	12	18	6	12	18	6	12	18
Antananarivo:												
Peer only	20.0	22.4	12.9	20.0	10.8	12.4	46.1	38.0	34.1	58.7	50.2	44.2
Peer + clinic	13.8	13.1	9.6	14.7	11.7	9.6	44.3	35.6	34.0	52.2	45.5	39.2
Tamatave:												
Peer only	19.3	12.2	10.6	8.4	5.9	9.6	28.1	21.0	18.8	42.9	34.1	32.1
Peer + clinic	21.6	13.3	12.9	12.6	7.1	10.3	26.0	19.7	29.6	43.9	33.6	42.1

Aggregated outcome is defined as a positive result if any of STI outcomes is positive, a negative result if all types of STI outcomes are negative, and a missing result if any STI outcome is missing and none are positive.

Table 3 Odds ratio estimates of the effect of peer education+clinic-based counselling versus peer education only on aggregate STI prevalence at month 18: overall estimate and by site

Model	OR estimate (95% CI)
Overall estimate*	1.09 (0.81 to 1.48)
At Antananarivo	0.82 (0.55 to 1.22)
At Tamatave	1.54 (1.00 to 2.38)

*Obtained from a model that adjusts for main effects of site and Phase 1 intervention only.
OR, odds ratio; CI, confidence interval

resolved at the start of each study phase. To the extent infections did not clear with treatment in the previous phase, actual prevalence of new infections might be lower than reported. This effect would be equivalent across study groups, however, and should not affect the study outcomes.

We conclude that peer education could be as effective as more clinically-intensive strategies for adding the female condom to male condom promotion interventions. Nonetheless, persistently high STI prevalence and frequent unprotected sex are disappointing. Our results support previous reports of the largely intractable tendency of sex workers to refrain from using condoms with their personal partners.[3–5] Offering STI testing and treatment to sex workers' steady partners is an intervention worthy of consideration. More generally, health care providers' influence on women's condom use is limited. Still needed are complementary strategies such as prevention education targeting men and public campaigns stimulating widespread recognition of the importance of condom use in sexual encounters with non-steady partners.

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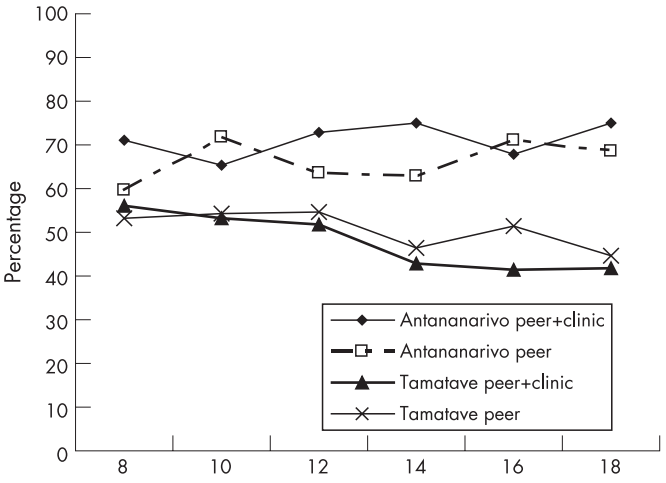

Figure 3 Percentage of participants reporting any female condom use in last 30 days with clients, by month of follow-up, by site and by intervention group.

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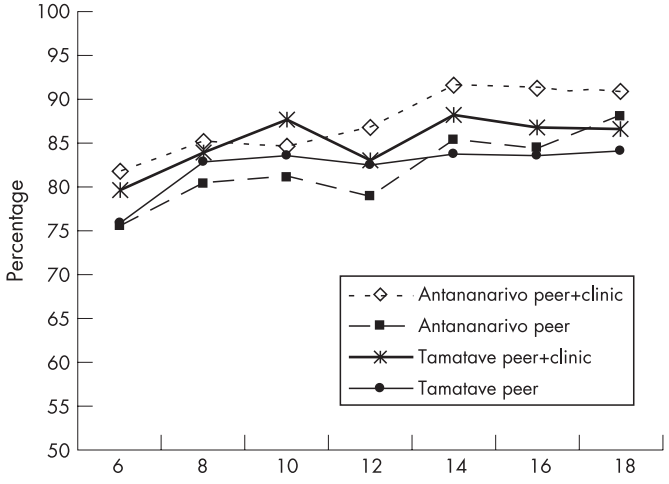

Figure 2 Mean percentage of sex acts with clients in last 30 days protected by male and female condoms, stratified by month of follow-up visit and intervention group.

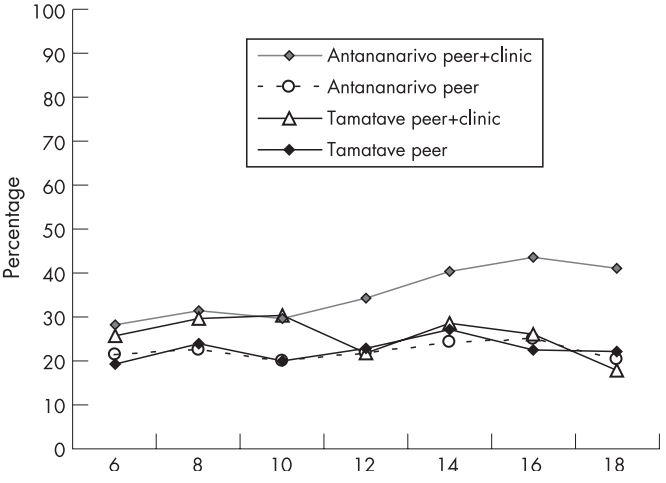

Figure 4 Percentage of participants reporting use of protection in last sex act with non-paying partner, by month of follow-up, by site and by intervention group.

Key messages

- Peer promotion of male and female condom use to a sex worker population appears to be as effective as a more intensive clinic-based counselling intervention for encouraging use of those methods.
- Interventions for introducing female condoms might not need to be particularly intensive in populations that are already well exposed to male condom promotion and have adopted preventive behaviours.
- Lay health workers could potentially play an important role in encouraging male and female condom use, thereby freeing clinicians to attend to other STI control interventions such as diagnosis and treatment.

REFERENCES

1 **Thomsen S**, Stalker M, Toroitich-Ruto C. Fifty ways to leave your rubber: how men in Mombasa rationalise unsafe sex. *Sex Transm Infect* 2004;**80**:430–434.
2 **Varga C**. The condom conundrum: barriers to condom use among commercial sex workers in Durban, South Africa. *Afr J Reprod Health* 1997;**1**:74–88.
3 **Wojcicki J**, Malala J. Condom use, power and HIV/AIDS risk: sex-workers bargain for survival in Hillbrow/Joubert Park/Berea, Johannesburg. *Soc Sci Med* 2001;**53**:99–121.
4 **French P**, Latka M, Gollub E, *et al.* Use-effectiveness of the female condom versus male condom in preventing sexually transmitted diseases in women. *Sex Transm Dis* 2003;**30**:433–439.
5 **Fontanet AL**, Saba J, Chandelying V, *et al.* Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: results from a randomized controlled trial. *AIDS* 1998;**12**:1851–1859.
6 **Welsh M**, Feldblum P, Kuyoh MA, *et al.* Condom use during a community intervention trial in Kenya. *Int J STD AIDS* 2001;**12**:469–74.
7 **Thomsen SC**, Ombidi W, Toroitich-Ruto C, *et al.* A prospective study assessing the effects of introducing the female condom in a sex worker population in Mombasa, Kenya. *Sex Transm Infect* 2006;**82**:397–402.
8 **Musaba E**, Morrison C, Sunkutu MR, *et al.* Long-term use of the female condom among couples at high risk of human immunodeficiency virus infection in Zambia. *Sex Transm Dis*, **25**:260–4.
9 **Latka M**, Gollub E, French P, *et al.* Male-condom and female-condom use among women after counseling in a risk-reduction hierarchy for STD prevention. *Sex Transm Dis* 2000;**27**:431–437.
10 **Hoffman S**, Mantell J, Exner TM, *et al.* The future of the female condom. *Perspect Sex Reprod Health* 2004;**36**:120–126.
11 **Artz L**, Macaluso M, Brill I, *et al.* Effectiveness of an intervention promoting the female condom to patients at sexually transmitted disease clinics. *Am J Public Health* 2000;**90**:237–244.
12 **Vijayakumar G**, Mabude Z, Smit J, *et al.* A review of female-condom effectiveness: patterns of use and impact on protected sex acts and STI incidence. *Int J STD AIDS* 2006;**17**:652–659.
13 **Gollub E**. The female condom: tool for women's empowerment. *Am J Public Health* 2000;**90**:1377–1381.
14 **Gollub E**, French P, Latka M, *et al.* Achieving safer sex with choice: studying a women's sexual risk reduction hierarchy in an STD clinic. *J Womens Health Gend Based Med* 2001;**10**:771–783.
15 **Artz L**, Macaluso M, Kelaghan J. An intervention to promote the female condom to sexually transmitted disease clinic patients. *Behav Mod* 2005;**29**:318–369.
16 **Witte S**, El-Bassel N, Gilbert L, *et al.* Promoting female condom use to heterosexual couples: findings from a randomized clinical trial. *Perspect Sex Reprod Health* 2006;**38**:148–154.
17 **Sly D**, Quadagno D, Harrison D, *et al.* Factors associated with use of the female condom. *Fam Plann Perspect* 1997;**29**:181–184.
18 **Kalichman S**, Williams E, Nachimson D. Brief behavioral skills building intervention for female controlled methods of STD-HIV prevention: outcomes of a randomized clinical field trial. *Int J STD AIDS* 1999;**10**:174–181.
19 **Van Deventer N**, Gonzales V, Merzel C, *et al.* Effect of an STD/HIV behavioral intervention on women's use of the female condom. *Am J Public Health* 2002;**92**:109–115.
20 **Ford N**, Koetsawang S. A pragmatic intervention to promote condom use by female sex workers in Thailand. *Bull World Health Organ* 1999;**77**(11):888–94.
21 **Feldblum P**, Hatzell T, Van Damme K, *et al.* Results of a randomised trial of male condom promotion among Madagascar sex workers. *Sex Transm Infect* 2005;**81**:166–173.
22 **Moher D**, Schultz K, Altman D. The CONSORT statement: revised recommendations for improving the quality of parallel-group randomised trials. *Lancet* 2001;**357**:1191–4.
23 **Catania J**, Gibson D, Chitwood D, *et al.* Methodological problems in AIDS behavioral research: influences on measurement error and participation bias in studies of sexual behavior. *Psychol Bul* 1990;**108**:339–362.
24 **Crosby R**. Condom use as a dependent variable: measurement issues relevant to HIV prevention programs. *AIDS Educ Prev* 1998;**10**:548–557.
25 **Sheeran P**, Abraham C. Measurement of condom use in 72 studies of HIV-preventive behaviour: a critical review. *Patient Educ Coun* 1994;**24**:199–216.
26 **Center for Health and Gender Equity**. Prevention now: expanding access to the female condom. http://www.genderhealth.org/pubs/prevnowaccess.pdf (accessed November 2006).
27 **Noar SM**, Cole C, Carlyle K. Condom use measurement in 56 studies of sexual risk behavior: review and recommendations. *Arch Sex Behav* 2006;**35**:327–45.